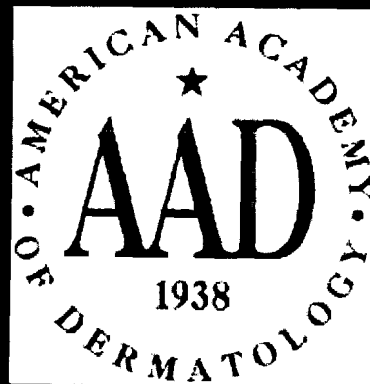


**ATTACHMENT 1**

# **High SPF Sunscreens: a Dermatologist's Viewpoint**

**Mark Naylor, M.D.**



# **Theoretical Effect of SPF on Exposure Reduction**

**Lifetime UV exposure reduction in  
the general population can be  
accomplished by low SPF (4-15)  
preparations**

**Low SPF preparations are  
inadequate for high risk  
individuals**

# **High Risk Individuals**

**Individuals with actinic keratoses or skin cancer**

**Individuals at high risk for melanoma**

**Individuals with outdoor occupations**

**Individuals who desire minimal photoaging**

**Individuals with photosensitivities**

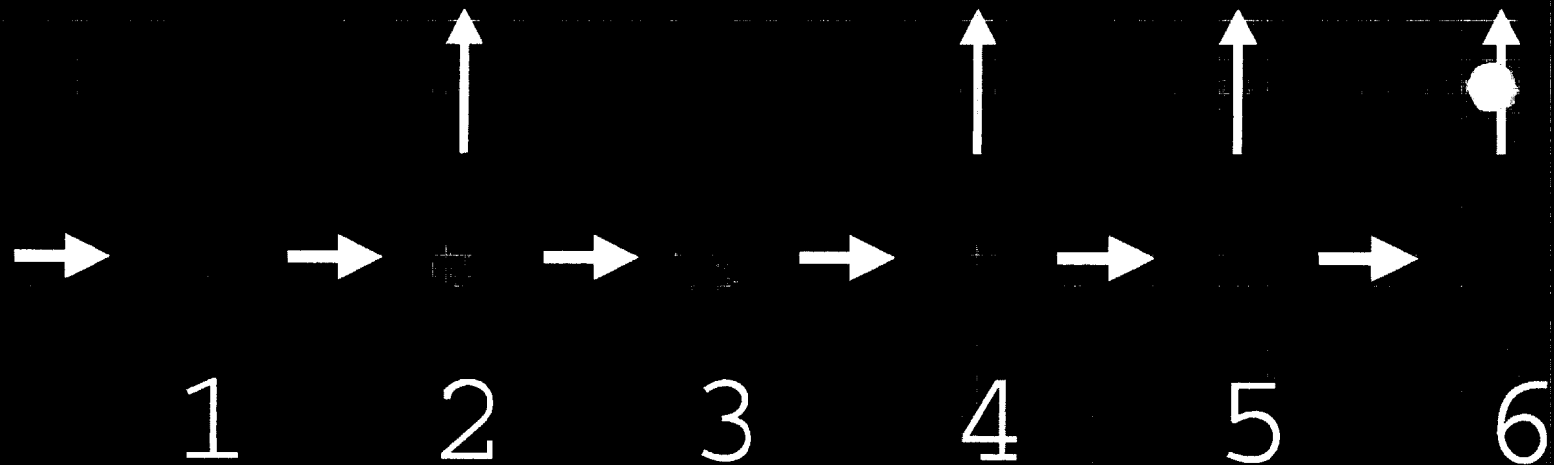
# Melanocytic Progression

Genetic abnormalities are UV-induced

Complete protection from UV halts progression •

Visible Lesions

Number of  
Significant  
Genetic  
Abnormalities



# High Risk vs. Low Risk for Skin Cancer

## High Risk

Many genetic abnormalities

One UV “hit” may generate a tumor

Intolerant to UV damage

>SPF 30 for maximum effect

## Low Risk

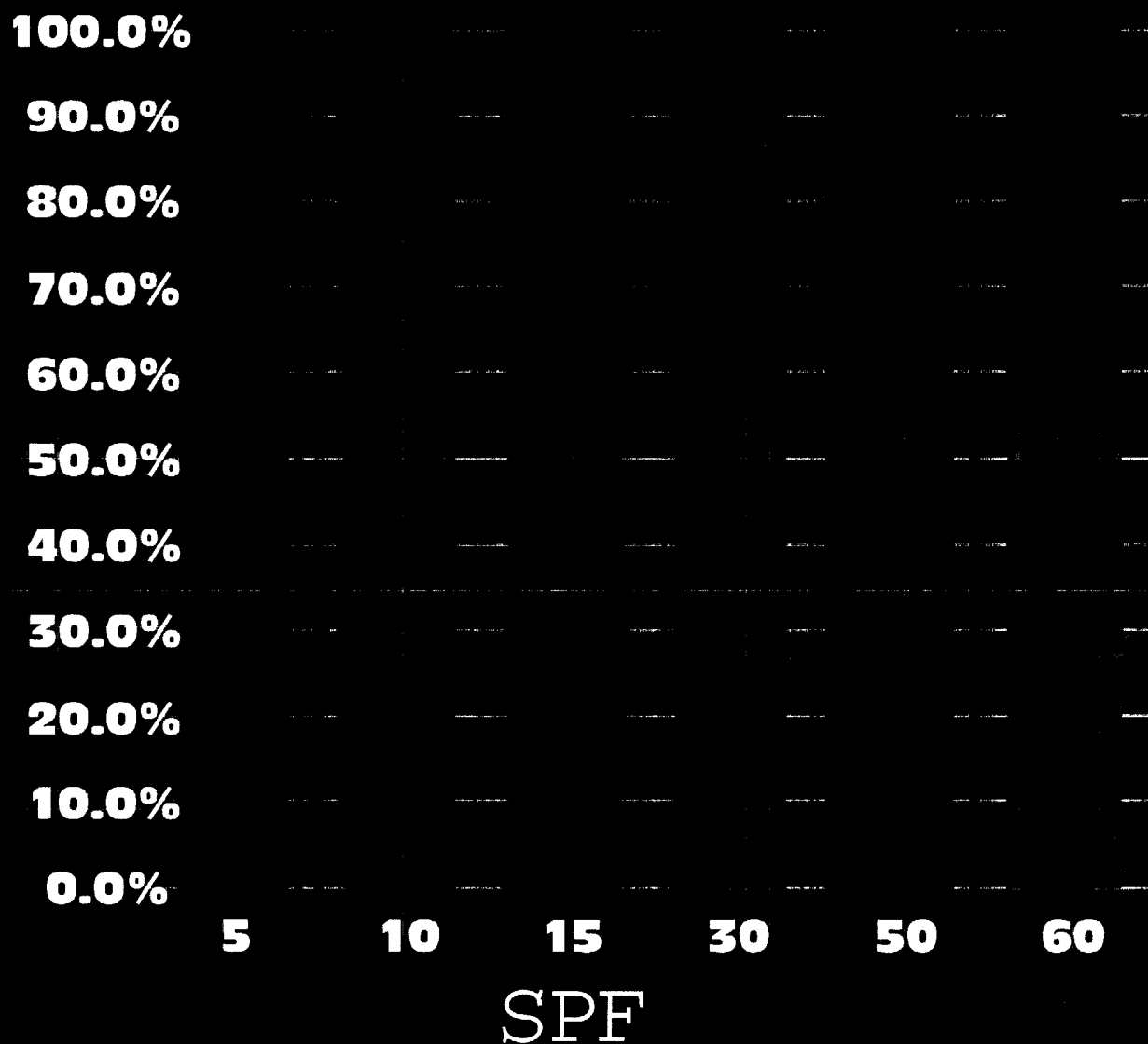
No or few genetic abnormalities

Many “hits” to generate a tumor

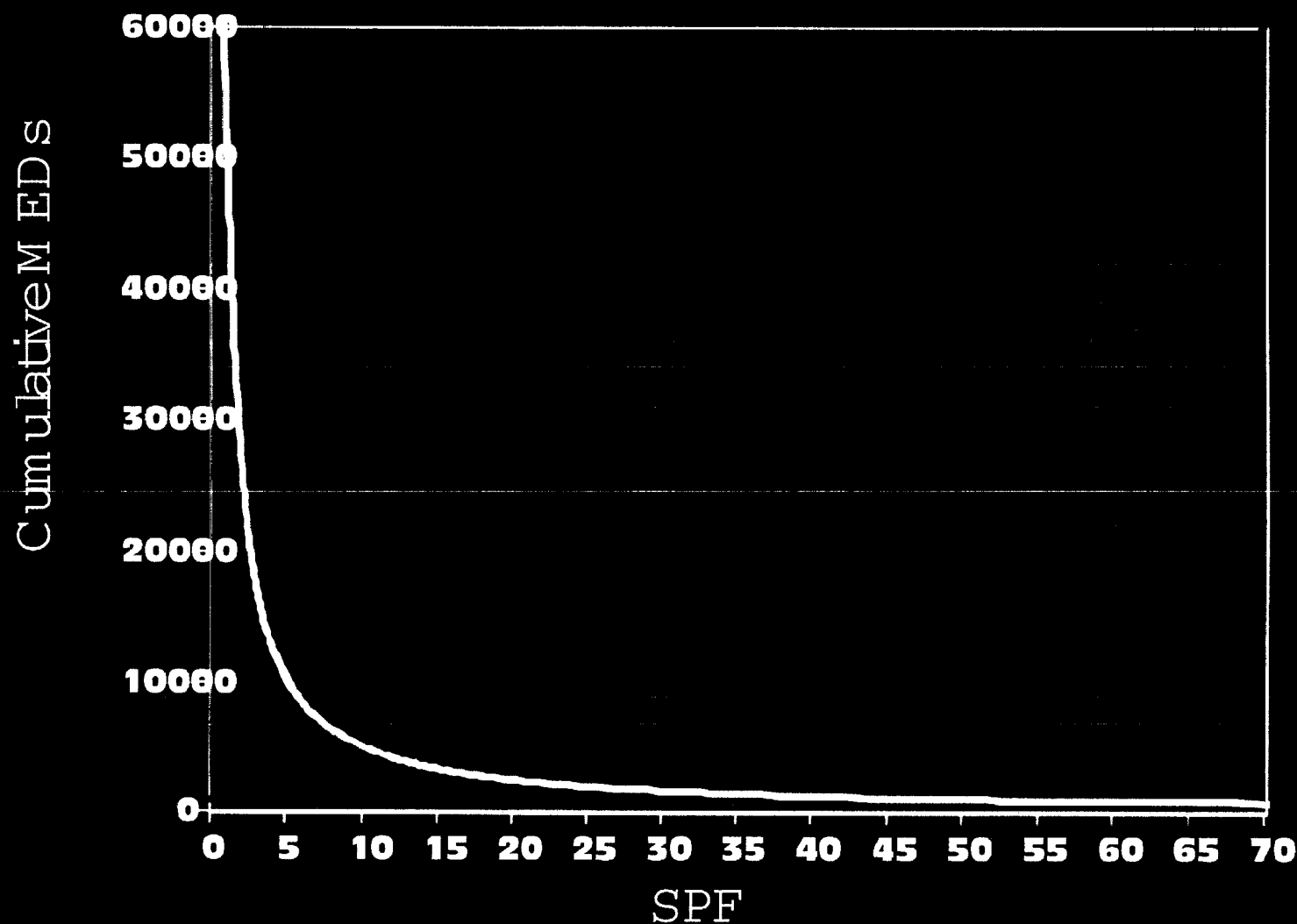
Tolerant to UV damage

SPF 30 adequate for lifetime cancer prevention?

# Theoretical Effect of SPF on Incident UV



# Need for Greater Protection with Higher Cumulative UV Doses



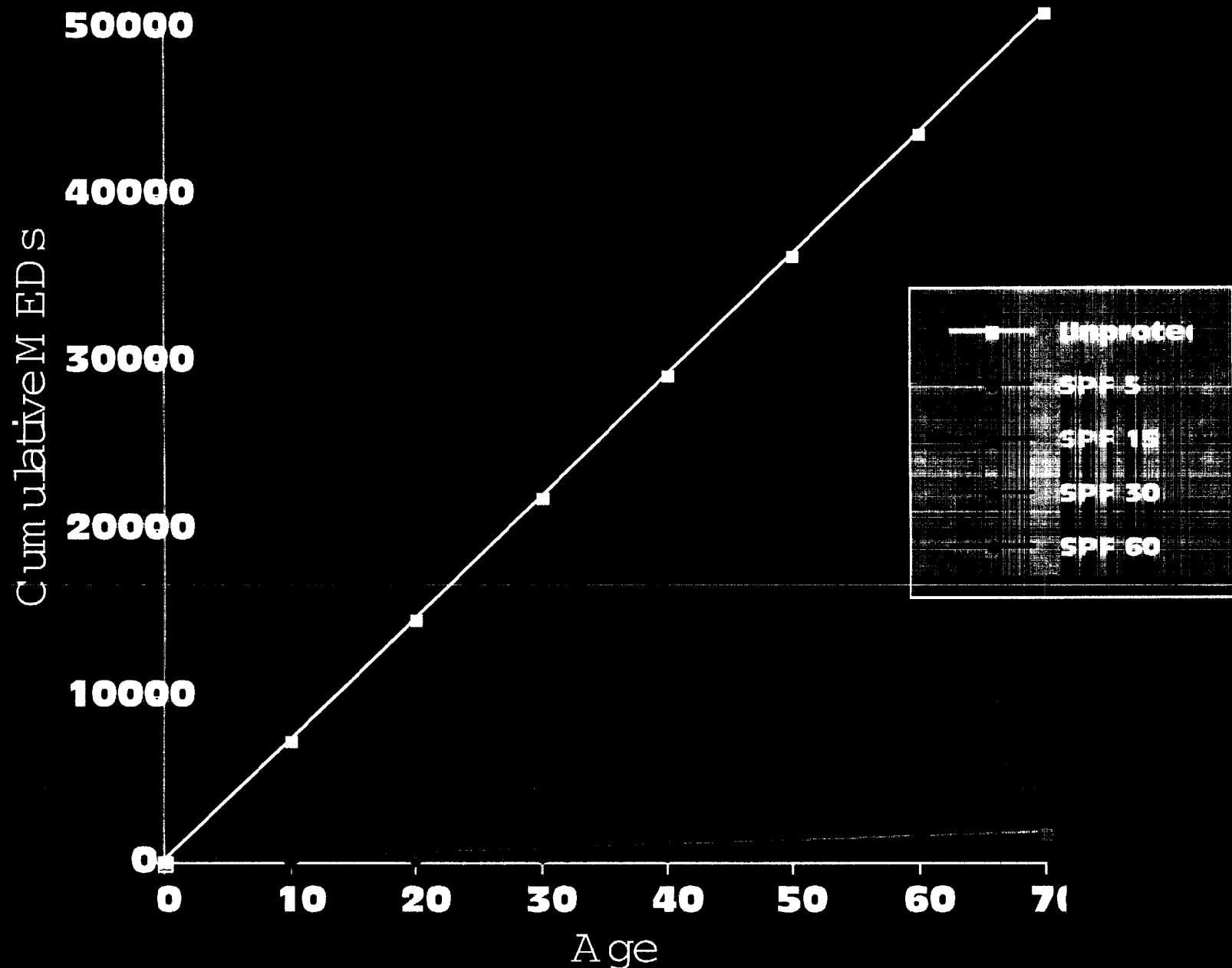


# Annual MEDs in Selected U.S. Cities



Source: Nole GE, Johnson AW, Cheney MC, Znaiden A. Cumulative lifetime UVR exposure in the United States and the effect of various levels of sunscreen protection. *Cosmetic Dermatology*. 1999;12:22-26.

# Theoretical Lifetime MED Reductions



# Lifetime MED Values<sup>1</sup>

SPF	0	5	10	15	30	50	60
Age (yr)	0	0	0	0	0	0	0
10	7266	1453	727	484	242	145	121
20	14532	2906	1453	969	484	291	242
30	21798	4360	2180	1453	727	436	363
40	29064	5813	2906	1938	969	581	484
50	36330	7266	3633	2422	1211	727	606
60	43596	8719	4360	2906	1453	872	727
70	50862	10172	5086	3391	1695	1017	848

<sup>1</sup>Daily Ideal Use; Fort Worth, TX., 10% Total UV

# Two-Year SPF Comparison<sup>1</sup>

SPICUMEDs (2 yr)	Improvement Over Preceding SPF	Absolute Improvement	Apparent Improvement Over Previous SPF
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0	1453			
5	291	80.0%	80.0%	
10	145	50.0%	90.0%	10.0%
15	97	33.3%	93.3%	3.3%
20	48	50.0%	96.7%	3.3%
25	29	40.0%	98.0%	1.3%
30	24	16.7%	98.3%	0.3%

<sup>1</sup>Daily Ideal Use; Fort Worth, TX., 10% Total Use

# Important Goals for Sunscreen Use

Photosensitivity  
Protection

Cancer  
Prevention

Genetic  
Damage  
Prevention

Erythema  
Prevention